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EXAMINER	
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1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,031	MALCOLM ET AL.	
	Examiner	Art Unit	
	DANAH AL-AWADI	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3, 6-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 6-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed 07/23/2009. The Examiner acknowledges the following:

Claims 4 and 5 have been cancelled. Claim 2 was previously cancelled.

Claims 1, 3, 6, 7, and 8, have been amended. Pending claim 1 incorporates the limitation "wherein each hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5 mm and the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750 mm^2.

Thus, claims 1, 3, 6-18 now represent all claims currently pending.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for consideration.

WITHDRAWN REJECTIONS

Rejection under 35 USC 102(b)

Applicants' amendments to the instant claims, namely claim 1, render moot the rejection to claims 1, 3, 6, 7, 13, and 17, under 35 USC 102 (b) as being anticipated by Zaffaroni US Patent 3,993,072. Thus, said rejection has been **withdrawn.**

Applicants' amendments to the instant claims, namely claim 1, render moot the rejection to claims 1, 3, 5, 13, and 16-18, under 35 USC 102 (b) as being anticipated by Saleh et al. US Patent 5,972,372. Thus, said rejection has been **withdrawn.**

Rejection under 35 USC 103(c)

Applicants' amendments to the instant claims, deleting claim 4, render moot the rejection to claim 4 under 35 USC 103 (c) as being unpatentable over Theeuwes modified by Saffron and further in view of Brooke US Patent 3,924, 622). Thus, said rejection has been **withdrawn.**

NEW REJECTIONS

In light of Applicant's amendments, most notably to claim 1, the following rejections have been newly added:

Claim Rejections - 35 USC § 103

Claims 1, 3, 6, 7, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni (US 3,993,072).

With respect to claim 1, Zaffaroni discloses in Example 1, an implant device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent (progesterone) or a prodrug thereof, dispersed in a hydrophobic elastomeric polymer (polydimethylsiloxane), and a porous sheath (wall) that surrounds the at least one reservoir, wherein the implant device is an intravaginal drug delivery device for administration into a vaginal environment (Examples 16 and 18; col. 23, lines 37-38; col. 24, lines 17-20). Zaffaroni further discloses the pore structure of the sheath (wall) further includes continuous pores, wherein a pore has an opening on both faces of the sheath connected therethrough thereby forming continuous diffusional paths (col. 10, lines 39-49). Therefore, the sheath is considered to discontinuously surround the at least one reservoir so as to define at least one hole or opening, the at least one hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment.

Zaffaroni does not explicitly disclose that the hole or opening has a diameter range of 0.5 to 6.5 mm and that the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750mm 2, however Zaffaroni does teach that the rate of passage of drug through the media in the microporous wall material is generally dependent, in the case of diffusion, on the solubility of the drug in the media, as well as on the diffusion coefficient and on the size of the pores and the porosity and tortuosity of the material. Furthermore, Zaffaroni teaches that the pore structure can be substantially cylindrical. It would have been prima facie obvious to one of ordinary skill in the art to optimize the diameter of the hole or opening. One would have been motivated to do so because Zaffaroni teaches that the rate of passage of drug through the media in the microporous wall is dependent on the size of the pores (Col. 8. lines 55-63 and Col. 9 lines 31-36).

Furthermore, with regard to the limitation(s) which states "wherein each hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5mm and the total surface area of the reservoir exposed to the vaginal environment through the one ore more holes or openings, when in use, is in a range of 1 to 750 mm^2"; absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the diameter ranges and surface area of the reservoir.

With respect to claim 3, Zaffaroni discloses the at least one hole or opening is on both faces of the sheath (wall) and is connected therethrough, therefore is considered to extend to the

surface of the at least one reservoir and/or extends partially into the at least one reservoir (col. 10, lines 39-42).

With respect to claim 6, Zaffaroni discloses the continuous pores, such as straight continuous pores, has the at least one hole or opening is on both faces of the sheath (wall) and is connected therethrough and forms a diffusional path for passage through the sheath (col. 10, lines 39-49), therefore is considered to extend through the sheath substantially normal to the reservoir surface. The examiner interprets the continuous pores to be openings extending through the sheath (wall) to at least one reservoir.

With respect to claim 7, Zaffaroni discloses in Fig. 8, the device is a ring that is substantially circular in transverse cross-section, and the sheath has a multiple micropores formed with continuous diffusional paths through the sheath (col. 24, lines 20-22). Zaffaroni further describes the pore structure of the sheath having continuous pores, where each pore has an opening on both faces of the sheath (wall) and is connected therethrough (col. 10, lines 39-42). Therefore, the examiner interprets the at least one hole (continuous pore/continuous diffusional path) extends substantially radially through the sheath at the inner circumference of the ring or at the outer circumference of the ring.

With respect to claim 8, Zaffaroni addresses all the limitations of claim 7, and further discloses multiple pores formed with continuous diffusional paths (continuous pores with openings) along the inner or outer circumference of the intravaginal drug delivery device (col. 24, lines 17-23).

However, Zaffaroni fails to expressly disclose the exact number of holes or openings. Zaffaroni further teaches the porosity affects the diffusion rate of the drug through the media in the wall (col. 9, lines 31-36).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the number of holes or openings in the inner or outer circumference of the intravaginal drug delivery device in order to attain the desired diffusion rate.

With respect to claim 13, Zaffaroni discloses in Example 18, the device is a ring (toroid shape).

With respect to claim 17, Zaffaroni discloses the intravaginal device can be made by forming a reservoir by dispersing at least one pharmacologically active agent in a pharmaceutically acceptable hydrophobic elastomer polymer, curing the reservoir, and applying a sheath to partly surround the reservoir (col. 20, lines 28-37).

Claims 1, 3, 13 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Saleh et al. (US 5,972,372).

With respect to claim 1, Saleh et al. discloses in Figs. 4A-4C and 5, an intravaginal drug delivery device for administration into a vaginal environment, the device comprising at least one reservoir (42) (channel that includes elements 44, 49 of Figs. 4A-4C and elements 59, 54 and 53 of Fig. 5), the at least one reservoir containing at least one pharmacologically active agent or a prodrug thereof (44, 54) dispersed in a polymer, and a sheath (40, 52) discontinuously surrounding the at least one reservoir so as to define at least one hole or opening (opening of the channel), the at least one hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the

vaginal environment (col. 5, line 61 – col. 6, line 12; col. 6, lines 37-61). Saleh further teaches that an unsealed core can be made. For example, Saleh et al. teaches providing a vaginal ring body containing a first polymeric material having at least one hollow internal channel defining an opening to the exterior of said body and which channel is adapted to receive a intravaginally administrable drug-containing core through the opening; providing a core containing a pharmaceutically effective amount of the intravaginally administrable drug dispersed in a second polymeric material, wherein the first and second polymeric materials may be the same or different; and positioning the core in the channel to assemble the vaginal ring. (Col. 3, lines 13-27). In this embodiment there is no mention of a sealant and therefore Saleh et al. suggests an unsealed core can be made. Saleh et al. does teach that the hollow channel or ring may also contain a sealant, but the sealant can be for the sole purpose of securing the core in the hollow channel of the ring body. (col. 3, lines 6-12). Saleh et al. further teaches in col. 6, lines 46-57, the polymer is a hydrophobic elastomeric polymer in a preferred embodiment, and Examples 2-7 demonstrates the hydrophobic elastomeric polymer being polydimethylsiloxane. Saleh et al. discloses the at least one hole or opening is substantially cylindrical (channel having a diameter) with a diameter in the range of about 0.5mm - 6.5 mm (col. 9, lines 48-51; Example 6). Saleh does not disclose the claimed surface area, however it would have been obvious to one of ordinary skill in the art to modify the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, in order to further modify the desired diffusion rate of the drug from the reservoir, as taught by Saleh et al. (col. 1, lines 35-42).

With respect to claim 3, Saleh et al. discloses the at least one hole or opening extends to the surface of the at least one reservoir and/or extends partially into the at least one reservoir (col. 5, line 65 - col. 6, line 3).

With respect to claim 13, Saleh et al. discloses the device is a partial or complete toroid shape (col. 6, line 4).

With respect to claim 16, Saleh et al. discloses the sheath comprises at least one additional pharmacologically active agent (col. 6, lines 33-36; col. 7, lines 42-46).

With respect to claim 17, Saleh et al. discloses forming a reservoir (core) by dispersing at least one pharmacologically active agent in a pharmaceutically acceptable hydrophobic elastomeric polymer (polydimethylsiloxane), curing the reservoir (room temperature vulcanizing), and applying a sheath to partly surround the reservoir (insertion of the core) (Example 2; col. 4, lines 14-15; col. 7, lines 56-59; col. 8, lines 4-8).

With respect to claim 18, Saleh et al. discloses injecting a reservoir material into a hollow sheath (col. 4, lines 24-29; col. 8, lines 13-23; Example 7).

Claims 1, 3, 6, 9-12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (US 3,926,188) in view of Chappaz et al. (US 2,962,023).

With respect to claim 1, Baker et al. discloses in Fig. 5, a drug delivery device for administration to an environment, the device comprising at least one reservoir (15), the at least one reservoir containing at least one pharmacologically active agent (14) or a prodrug thereof dispersed in a polymer, and a sheath (21) discontinuously surrounding the at least one reservoir

so as to define at least one hole or opening (end surface opening for element 21), the at least one hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the environment (col. 4, lines 27-48). Baker et al. further discloses the polymer being a hydrophobic elastomeric polymer, such as polydimethylsiloxane, polyvinyl chloride and poly(ethylene-co-vinyl acetate) (col. 5, lines 52, 57-58, 60-61; col. 6, lines 6-7), and further demonstrates a drug incorporated into a hydrophobic elastomeric polymer in Example 1. Baker et al. teaches surface area but does not teach the claimed diameter of the pores or the claimed surface area of the reservoir, however absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the particle size. Furthermore, Chappaz et al. teaches that the size of the perforations (which are cylindrical in shape) may be varied to accommodate the type of medicament and quantity or rate at which the medicament is to be dispensed (Figures 1 and 3, Col 3. lines 6-9).

Baker et al. fails to expressly disclose using the cylindrical drug delivery device in Fig. 5 in a vaginal environment.

However, Baker et al. does disclose using the drug delivery device in a vaginal environment, and when used in such an environment, the device will be sized and shaped accordingly (col. 6, lines 39-43).

Chappaz et al. teaches it is known in the art to use cylindrical drug delivery devices in the vaginal environment (col. 2, lines 38-40; col. 3, lines 19-23).

It would have been obvious to one of ordinary skill in the art to use the cylindrical drug delivery device of the modified Baker et al. in a vaginal area in order to be compatible with the size and shape of the insertion site for the predictable result of comfortably treating the vaginal area.

With respect to claim 3, the modified Baker et al. discloses in Fig. 5, the at least one hole or opening (end surface opening for element 21) extends to the surface of the at least one reservoir (15) and/or extends partially into the at least one reservoir.

With respect to claim 6, the modified Baker et al. discloses in Fig. 5, the at least one hole or opening (end surface opening for element 21) extends through the sheath (21) substantially normal to the reservoir surface (22, 23).

With respect to claim 9, the modified Baker et al. discloses in Fig. 5, the device is a substantially cylindrical rod device, and said at least one hole or opening is provided at each terminal end (22, 23) of the rod.

With respect to claim 10, the modified Baker et al. discloses in Fig. 5, the rod device defines a right circular cylinder and each base of the rod is partly or fully exposed, to define said holes.

With respect to claim 11, the modified Baker et al. addresses all the limitations of claim 9, however fails to expressly disclose additional holes or openings provided that extend substantially radially through the sheath.

Chappaz et al. discloses in Fig. 2, a cylindrical intravaginal drug delivery device for use in a vaginal cavity, having at least one hole or opening at each of the terminal ends and additional holes or openings provided extending substantially radially through the sheath (10).

It would have been obvious to one of ordinary skill in the art to modify the device of the modified Baker et al. to include additional holes or openings extending substantially radially through the sheath in order to deliver the desired pharmacologically active agent along the entire device to cover more surface area of the vaginal cavity wall for medication or to diffuse the medication in a desired direction, as taught by Chappaz et al. (col. 1, lines 32-35; col. 3, lines 1-6, 19-23).

With respect to claim 12, the modified Baker et al. addresses all the limitations of claim 11, however fails to expressly disclose there are one to thirty of said further holes or openings along the circumference of the rod.

Chappaz et al. teaches the diffusion rate and the amount of drug that is to be dispensed from the reservoir is dependent on the number of holes in the sheath (col. 1, lines 36-42).

It would have been obvious to one of ordinary skill in the art to modify the number of additional holes or openings in order to further modify the desired diffusion rate of the drug from the reservoir, or to further modify the amount of drug to be dispensed, as desired, as taught by Chappaz et al. (col. 1, lines 36-42; col. 3, lines 6-9).

With respect to claims 14 and 15, the modified Baker et al. discloses the reservoir additionally comprises at least one pore-forming excipient (starch) (col. 6, lines 6-14).

Claims 1, 3, 6, and 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes (US 4,217,898) in view of Zaffaroni and Chappaz et al.

With respect to claim 1, Theeuwes discloses in Fig. 2, an intravaginal drug delivery device for administration into a vaginal environment, the device comprising at least one reservoir

(13), the at least one reservoir containing at least one pharmacologically active agent (19) or a prodrug thereof dispersed in a polymer, and a sheath (15) discontinuously surrounding the at least one reservoir so as to define at least one hole or opening (12), the at least one hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the environment (col. 4, lines 23-54; col. 5, lines 1-14).

Theeuwes fails to expressly teach an example wherein the drug is dispersed in a hydrophobic elastomeric polymer.

However, Theeuwes discloses various types of polymers as suitable materials for the reservoir, and further suggests using a hydrophobic elastomeric polymer (polyvinyl chloride) (col. 7, line 59).

It would have been obvious to one of ordinary skill in the art to modify the type of polymer used in order to provide the desired solubility of the pharmacologically active agent of the desired pharmacologically active agent used, as taught by Zaffaroni (col. 6, lines 12-22). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Theeuwes addresses all the limitations of claim 1, however fails to expressly disclose the shape and size of the at least one hole or opening.

Chappaz et al. discloses in Figs. 1, an intravaginal drug delivery device having a plurality of holes that are substantially cylindrical (round hole which inherently has a depth through a

sheath). Chappaz et al. further teaches the holes are 1/32 inch in diameter, therefore is within the claimed diameter range (col. 4, lines 5-8).

It would have been obvious to one of ordinary skill in the art to modify the shape and size of the at least one hole or opening in order to further modify the desired diffusion rate of the drug from the reservoir, or to further modify the amount of drug to be dispensed. Further, a change in size and shape is generally recognized as being within the level of one of ordinary skill in the art. *In re Rose*, 105 USPQ 237(CCPA 1955); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

With respect to claim 3, the modified Theeuwes discloses in Fig. 2, the at least one hole or opening (12) extends to the surface of the at least one reservoir (13) and/or extends partially into the at least one reservoir.

With respect to claim 6, the modified Theeuwes illustrates in Fig. 2, the at least one hole or opening (12) extends through the sheath (15) substantially normal to the reservoir surface.

With respect to claims 7 and 13, the modified Theeuwes addresses all the limitations of claim 1, and further illustrates in Fig. 2, the at least one hole or opening located on the circumference of the device.

However fails to expressly disclose the device being a ring that is substantially circular in transverse cross-section.

However, Theeuwes discloses the drug delivery device can be sized and shaped depending on the desired environment it is intended to be used in, such as within a vaginal environment (col. 5, lines 1-4, 48-53).

Zaffaroni teaches it is known in the art for intravaginal drug delivery devices to be in a ring shape (toroid shape) (Example 18).

It would have been obvious to one of ordinary skill in the art to modify the shape of the device in order to lend itself for a comfortable uterine placement and retention, as desired. Further, a change in shape is generally recognized as being within the level of one of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Examiner further notes, the modification of the shape of Fig. 2 to be a ring shape would still include the at least one hole or opening on the outer circumference of the ring.

With respect to claim 8, the modified Theeuwes addresses all the limitations of claim 7, however fails to expressly disclose the number of holes along the inner or outer circumference of the intravaginal drug delivery device.

Chappaz et al. teaches the diffusion rate and the amount of drug that is to be dispensed from the reservoir is dependent on the number of holes in the sheath (col. 1, lines 36-42).

It would have been obvious to one of ordinary skill in the art to modify the number of additional holes or openings in order to further modify the desired diffusion rate of the drug from the reservoir, or to further modify the amount of drug to be dispensed, as desired, as taught by Chappaz et al. (col. 1, lines 36-42; col. 3, lines 6-9).

With respect to claim 9, the modified Theeuwes addresses all the limitations of claim 1, and further illustrates in Fig. 2 the device is a substantially cylindrical rod device.

The modified Theeuwes fails to expressly disclose the at least one hole or opening is provided at each terminal end of the rod.

However, Theeuwes does teach the rate of release for a given surface can be controlled and the direction of the release can be preselected by orienting the releasing surface (at least one hole or opening) to a preselected direction (col. 6, lines 25-28).

Therefore, it would have been obvious to one of ordinary skill in the art to include the at least one hole or opening at each terminal end of the rod in order to provide for the release of the drug in the desired directions, as demonstrated in Fig. 2 of Chappaz et al.

With respect to claim 10, the modified Theeuwes addresses all the limitations of claim 9, however fails to expressly disclose rod device defines a right circular cylinder.

Theeuwes teaches changing the size and shape of the device depending on the desired environment in which it is intended on being used (col. 5, lines 48-53).

It would have been an obvious design choice to modify the shape of the device since it has been held that a mere change in shape of an element is generally recognized as being within the level of one of ordinary skill in the art when the change in shape is not significant to the function of the combination. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Further, one of ordinary skill in the art would have been motivated to select the shape of the device for the purpose of providing for a comfortable placement and retention of the device in the vaginal environment.

With respect to claim 11, the modified Theeuwes addresses all the limitations of claim 9, and further illustrates in Fig. 2, multiple holes or openings (12) provided extending substantially radially through the sheath.

With respect to claim 12, the modified Theeuwes addresses all the limitations of claim 11, however fails to expressly disclose the number of holes along the inner or outer circumference of the intravaginal drug delivery device.

Chappaz et al. teaches the diffusion rate and the amount of drug that is to be dispensed from the reservoir is dependent on the number of holes in the sheath (col. 1, lines 36-42).

It would have been obvious to one of ordinary skill in the art to modify the number of additional holes or openings in order to further modify the desired diffusion rate of the drug from the reservoir, or to further modify the amount of drug to be dispensed, as desired, as taught by Chappaz et al. (col. 1, lines 36-42; col. 3, lines 6-9).

With respect to claims 14 and 15, the modified Theeuwes discloses the reservoir comprises at least one pore-forming excipient (solvent) (col. 7, lines 14-15).

RESPONSE TO ARGUMENTS

Applicant's arguments with regard to the rejection of claims 1, 3, 6, 7, 13, and 17 under 35 USC 102(b) as being anticipated by Zaffaroni US Patent 3,993,072,have been fully considered, but they are not persuasive. However in view of the amendment to claim 1, the rejection is now applied under 35 USC 103(a).

Applicant alleges that Zaffaroni does not disclose or suggest a device having the holes or openings of the present invention, i.e., having a diameter in the range of 0.5 to 6.5mm and the exposed recited surface area.

In response Examiner respectfully submits that Zaffaroni does not disclose the exact diameter range, but does provide motivation for optimizing the diameter range. It would have been prima facie obvious to one of ordinary skill in the art to optimize the diameter of the hole or opening. One would have been motivated to do so because Zaffaroni teaches that the rate of passage of drug through the media in the microporous wall is dependent on the size of the pores (Col. 8. lines 55-63 and Col. 9 lines 31-36).

Absent evidence of criticality, since the vales of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the diameter ranges.

Applicant's arguments with regard to the rejection of claims 1, 3, 5, 13, and 16-18 under 35 USC 102(b) as being anticipated by Saleh et al. US Patent 5,972,372 ,have been fully considered, but they are not persuasive. However in view of the amendment to claim 1, the rejection is now applied under 35 USC 103(a).

Applicant alleges that pending claim 1 requires that no portion of the drug-containing core is exposed to the exterior of the vaginal ring body and that Saleh might suggest that an unsealed core could be made, but that no such embodiment is disclosed by Saleh.

In response Examiner respectfully submits that the reference of Saleh as a whole must be considered, and that Saleh does suggest an unsealed core could be made. For example, Saleh et al. teaches providing a vaginal ring body containing a first polymeric material having at least one hollow internal channel defining an opening to the exterior of said body and which channel is adapted to receive a intravaginally administrable drug-containing core through the opening;

providing a core containing a pharmaceutically effective amount of the intravaginally administrable drug dispersed in a second polymeric material, wherein the first and second polymeric materials may be the same or different; and positioning the core in the channel to assemble the vaginal ring. (Col. 3, lines 13-27). In this embodiment there is no mention of a sealant and therefore Saleh et al. suggests an unsealed core can be made. Saleh et al. does teach that the hollow channel or ring **may** also contain a sealant, but the sealant can be for the sole purpose of securing the core in the hollow channel of the ring body. (col. 3, lines 6-12).

Applicant's arguments with regard to the rejection of claims 1, 3, 6, 9-12, 14, and 15 under 35 USC 103(a) over Baker et al. US Patent 3,926,188 in view of Chappaz et al. 2,962, 023, have been fully considered, but they are not persuasive.

Applicant alleges that Baker teaches a drug that should have a low water solubility which differs from the presently claimed invention that provides substantial drug delivery from the core to the vaginal environment and is capable of delivering of relatively hydrophilic and/or large molecular weight products in milligram doses on a daily basis.

In response, Examiner respectfully submits that there is no recitation in claim 1 that the drug be hydrophilic. Section 2145 VI of the MPEP states "Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Baker teaches that the degree of water solubility will in many instances depend on the permeability of matrix material to water. If the matrix material has a high permeability to water, the water solubility of the drug should be correspondingly low and **vice versa** (i.e. the drug does not have to have a low water solubility)(Col. 4, lines 61-66).

Applicant's arguments with regard to the rejection of claims 1, 3, 6, and 13-15 under 35 USC 103(a) over Theeuwes US Patent 4,217,898 in view of Zaffaroni, have been fully considered, but they are not persuasive.

Applicant alleges that Theeuwes is directed to osmotic devices and for that osmotic device to work in an aqueous environment, the reservoir must be hydrophilic and the replacement of the hydrophilic polymer with a hydrophobic elastomeric polymer is not an obvious design choice.

In response Examiner respectfully submits that Theeuwes teaches materials useful for making microporous reservoirs which include selecting polyvinyl chloride, a hydrophobic elastomeric polymer, as a choice for use in the invention.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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